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### (54) Thrombectomy method and device.

(57) A method of and apparatus for removing a thrombus deposit from the cardiovascular system of a patient without the need to surgically access the location of the thrombus deposit via a cut-down or other surgical procedure. A catheter (12) is inserted percutaneously into the patient at a convenient location either directly or over a previously positioned guide wire. The distal end of the catheter is advanced under fluoroscopy to the site of the thrombus deposit. A balloon (14) is inflated to stabilize the position of the distal end of the catheter within the center of the vessel lumen. A flexible metal tube (118) conveys an extremely high pressure stream of sterile saline solution to at least one jet at the distal end of the catheter. At least one jet positions the thrombus deposit for emulsification by at least one other jet. By directing the jets toward the orifice of the large evacuation lumen of the catheter, a stagnation pressure is induced which propels the emulsion proximally for disposal. The rate of proximal flow of effluent is metered to correspond with the distal flow of saline solution to ensure minimal local impact on the vasculature at the site of the thrombus deposit.

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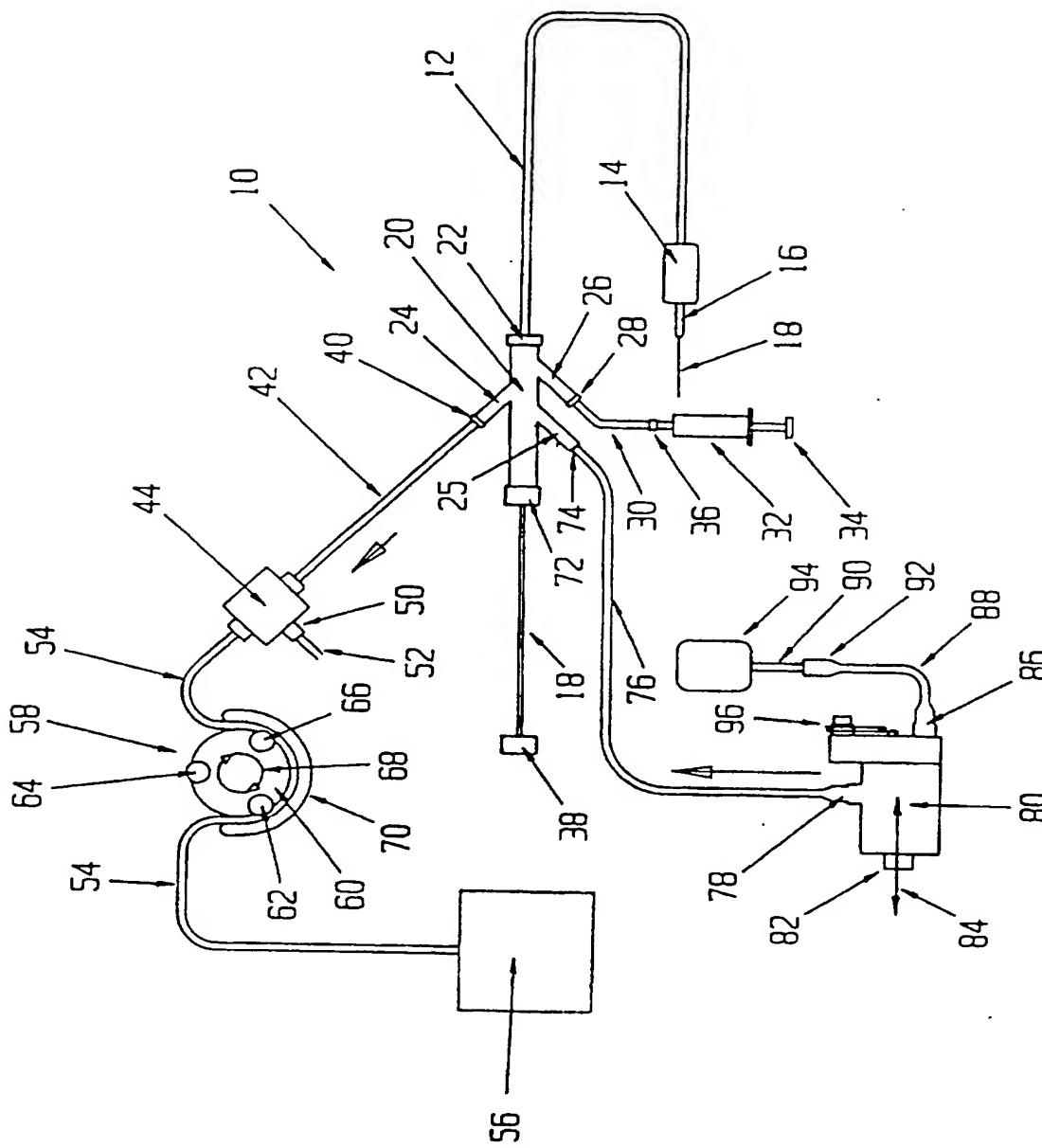


FIG. 1

## BACKGROUND OF THE INVENTION

**1. Field of the Invention** - The present invention relates generally to medical devices and procedures, and more particularly, relates to medical devices and procedures for removing thrombus deposits from the cardiovascular system.

**2. Description of the Prior Art** - Procedures and apparatus have been developed for use in removing tissue and various deposits. U.S. Patent No. 4,790,813 issued to Kensey and U.S. Patent No. 4,842,579 issued to Shiber describe techniques for the removal of plaque deposited in arteries by mechanical ablation using rotating cutting surfaces. These relatively traumatic approaches are directed to the treatment and removal of very hard substances.

In current medical procedures, thrombus deposits are often removed using a catheter such as is described in U.S. Patent No. 4,328,811 issued to Fogarty. In this system, a surgical cutdown is performed to access the vessel and allow catheter entry and advancement to a point beyond the deposit. The balloon is inflated and the catheter is withdrawn pulling the deposit along with it.

Pressurized fluids have also been used in the past to flush undesirable substances from body cavities. U.S. Patent No. 1,902,418 describes such a system for domesticated animals. The more modern approaches tend to use vacuum rather than gravity as the primary means for removal of the deposits or tissue and relatively low fluid pressures to cut into and fragment the substances to be ablated.

U.S. Patent No. 3,930,505 issued to Wallach describes a surgical apparatus for the removal of tissue from the eye of a patient. As with similar systems, Wallach uses a relatively low pressure jet of water (i.e. 15 to 3500 psi) to disintegrate the tissue, and a suction pump to perform the actual removal.

A similar approach applied to the cardiovascular system is discussed in U.S. Patent No. 4,690,672 issued to Veltrup. Veltrup also provides a much lower pressure jet of water (i.e. less than 450 psi) to fragment deposits. As with Wallach, Veltrup uses a vacuum pump for evacuation of the fragments. The distal end of the Veltrup catheter is readily repositionable to permit manual entrapment of the deposits to be fragmented.

## SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages of the prior art systems by providing apparatus which can be used in a surgical procedure performed entirely at positive pressures. This eliminates the need for a vacuum pump and provides the added safety feature of an intravascular environment which is always positively pressurized as during normal functioning of the cardiovascular system. This tends

to prevent collapse of the vessel. The system also controls the exposure of the vessel to over pressurization and prevent distension.

The following description is with particular reference to a preferred form of the present invention. In this form the only energy added to the system is via an extremely high pressure stream of saline solution. This stream serves to dislodge thrombus deposits, position them, and then emulsify them. Thrombus particles are attracted to the jet due to the localized high velocity and low pressure. Recirculation patterns and fluid entrainment bring the thrombus continually into close proximity of the jet. Once emulsified by the jet, the particles are removed by flow through the evacuation lumen generated as a result of stagnation pressure which is induced at the mouth of the evacuation lumen by the action of at least one fluid jet directed at and impinging on the lumen mouth.

The procedure can be practiced by percutaneously or intraoperatively entering the vascular system of the patient at a convenient location with a cannula. The catheter is inserted either directly or over a previously positioned guide wire and advanced under fluoroscopy to the site of the vascular occlusion or obstruction which generally contains an aggregation of blood factors and cells or thrombus deposit, which is normally identified by angiography. One or more balloons may be inflated to stabilize the distal end of the catheter and provide a degree of isolation of the area to be treated.

Sterile saline is pressurized by a disposable pump and directed through a flexible metallic tube within the catheter. One or more jets at the distal end of the catheter direct the pressurized stream generally in the direction of the mouth of the evacuation lumen at the distal end of the catheter with a component directed toward the vessel wall. One function of the jet(s) alone or in combination with a distal balloon, is to dislodge thrombus deposits from attachment to the vessel wall. Other functions of the jet(s) are to attract and emulsify (or disperse) the thrombus deposits and create the stagnation pressure which evacuates the emulsion.

A metering device is utilized at the proximal end of the evacuation lumen to regulate the flow rate of the emulsified thrombus out of the catheter. Because the entire system operates at a positive pressure, the output must be metered to prevent excess evacuation. Safety monitors turn the system off if one of the lumens or jets becomes clogged. An optional monitor at the distal end of the catheter can monitor power delivery and degree of blockage. An alternative embodiment of the invention provides an extra lumen for monitoring of temperature and/or pressure at the site of the thrombectomy. The evacuation lumen permits the passage of an angioplasty dilatation catheter or angioscope for intravascular viewing.

There is now described, by way of example and

with reference to the accompanying drawings, preferred embodiments of the thrombectomy device, catheter and method aspects of the present invention.

In the drawings:

**FIG. 1** is a schematic diagram of the overall system employing the present invention;

**FIG. 2a** is a mechanical view of disposable pump;

**FIG. 2b** is a cross-sectional view of the disposable pump;

**FIG. 2c** is a conceptual view of the safety monitor;

**FIG. 2d** is a cross-sectional view of an alternative

source of pressurized fluid;

**FIG. 3** is a cross-sectional view of the manifold;

**FIG. 4** is a conceptual view of the operation of the

manifold;

**FIG. 5a** is a close up view of the distal end of the catheter system of the present invention;

**FIG. 5b** is a longitudinal sectioned view of the dis-

tal end of the catheter system;

**FIG. 5c** is a view from the distal end of the cathe-

ter system;

**FIG. 6** is a cross-sectional view from immediately

proximal of the balloon;

**FIG. 7** is a cross-sectional view across the bal-

loon inflation port;

**FIG. 8** is a cross-sectional view taken distal of the

balloon;

**FIG. 9** is a cross-sectional view taken near the

distal tip of the catheter system;

**FIG. 10** is a longitudinal sectioned view of the dis-

tal end of a catheter system employing an alter-

native embodiment of the present invention;

**FIG. 11** is a cross-sectional view taken proximal

to the proximal balloon of the alternative embodi-

ment;

**FIG. 12** is a cross-sectional view of the alternative

embodiment from the inflation port of the proximal

balloon;

**FIG. 13** is a cross-sectional view of the alternative

embodiment taken distal of the proximal balloon;

**FIG. 14** is a cross-sectional view of the alternative

embodiment taken distal of the mouth of the

evacuation lumen;

**FIG. 15** is a cross-sectional view of the alternative

embodiment taken proximal of the distal balloon;

**FIG. 16a** is a sectioned view of the effluent safety

switch; and,

**FIG. 16b** is a cross-sectional view of the effluent

safety switch.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

**FIG. 1** is a schematic view of the preferred embo-

diment of catheter system 10 employing the present

invention. The details supplied herein should be taken

as representative and not limiting of the many embo-

diments which may be efficaciously employed within

the scope of the present invention.

Catheter system 10 has a standard two lumen catheter 12, which is extruded of a flexible material, such as polyolefin, PTFE, PVC, polyurethane, or other suitable material in the normal fashion. Near the distal end of catheter 12 is located inflatable balloon 14, which is preferably an elastic balloon having no predefined outside diameter size limitation upon inflation. In this manner, balloon 14 can conform to the exact dimensions of the vessel to hold distal end 16 of catheter 12 in a fixed position. Alternatively, inflatable balloon 14 can be an inelastic balloon with a pre-defined shape and size to permit it to be also used for dilatation as in transluminal angioplasty. Distal end 16 of catheter 12 is described in more detail below.

Guide wire 18, as manipulated by knob 38, is optionally available for positioning catheter 12 as an over-the-wire system. Guide wire 18 passes through the larger of the two lumens of catheter 12 as described in more detail below.

Manifold 20 is molded of a rigid plastic. The main branch couples to the larger of the lumens of catheter 12 and has a standard seal assembly 72 applied to the proximal end to sealingly engage guide wire 18.

Secondary branch 24 is also coupled to the larger lumen to provide for evacuation of the emulsified thrombus deposits. Secondary branch 24 sealingly engages distal end 42 of effluent tubing 54 via seal assembly 40. The operation of safety monitor 44, monitor switch 50, and cable 52 are explained in further detail below.

Flexible effluent tubing 54, including distal end 42, is coupled to safety monitor 44 as described in more detail below. The flow of effluent through flexible effluent tubing 54 is metered by rollers 62, 64, and 66 as rotated by rotor 60 in the direction of arrows 68. It must be emphasized that the effluent in flexible effluent tubing 54 is under pressure and, therefore, need not be pumped by peristaltic pump assembly 58, which merely restricts and meters the flow. This metering could equally well be accomplished with a timed mechanical valve (not shown) which controls the outflow rate. After metering, the effluent from flexible effluent tubing 54 is deposited in disposal bag 56.

Secondary branch 26 of manifold 20 is sealingly coupled to inflation tubing 30 by seal assembly 28. Inflation and deflation of inflatable balloon 14 is controlled by plunger 34 of syringe 32 in the customary manner. Syringe 32 is sealingly coupled to inflation tubing 30 by coupling assembly 36.

The saline solution used to emulsify the thrombus deposit is derived from standard sterile saline bag 94, which may be commercially available. The saline solution is transferred to disposable pump 80 via hypodermic needle 90 and tubing 88 and couplings 92 and 86. This is a low pressure fluid path.

Disposable pump 80 is a positive displacement piston pump. It is made to be completely disposable

for sanitary reasons. Disposable pump 80 is driven reciprocally as shown by arrows 84 by a motor driven cam (not shown) against cam bearing surface 82. As a convenient means to correlate infused volume of saline solution with volume of evacuated effluent, a single electric motor can be used to drive both disposable pump 80 and rotor 60. Control of these volumes is important to prevent rupture or collapse of the vessel wall. Closer tolerance control can be achieved at greater complexity using pressure and/or flow meters.

The high pressure output of disposable pump 80 is coupled to tubing 76 by high pressure coupling assembly 78. Tubing 76 has a flexible metallic inner tube inside of a flexible plastic or rubber outer tube as shown in more detail below. Tubing 76 is sealingly coupled to secondary branch 25 of manifold 20 by seal assembly 74. Safety monitor 96 operates as explained below to turn off the drive motor if the tubing or jets become clogged.

FIG. 2a is a partially sectioned view of disposable pump 80. As explained above, disposable pump 80 is designed to be discarded after a single use for sanitary reasons. It is a positive displacement piston pump. All referenced components are as previously described.

High pressure coupling assembly 78 is shown in greater detail to highlight that metallic tube 75 is brazed at point 77 to produce the required high pressure joint. Outer tubing 71 is a low pressure connection which may be attached with adhesive. The entire high pressure coupling assembly 78 is attached to disposable pump 80 with threads 73 and compressing a high pressure seal.

Safety monitor 96 comprises two safety features. Pressure plug 100 is attached to disposable pump 80 by threads 98. Pressure plug 100 is designed to release and vent the system to the atmosphere at pressures above 30,000 - 40,000 psi. The second safety feature serves to electrically disconnect the drive motor whenever the pressure is too high. Increased pump pressure forces contact 104 toward electrical contact with contact 106 as a result of pushing out of pressure plug 100 as attached at point 102 (shown in detail below), thereby closing the electrical circuit to a relay and turning off the drive motor. Insulators 95 and 97 maintain contacts 104 and 106 open under normal pressure conditions.

The saline input to the disposable pump includes a hypodermic needle 90 which penetrates a puncture port on a bag of saline. The saline is delivered through coupling 92 to tube 88 and through coupling 86 into the inlet of the disposable piston pump 80.

FIG. 2b is a cross-sectional view of disposable pump 80. As a matter of convenience the disposable pump 80 is oriented slightly different from FIG. 1. All referenced components are as previously described.

Cam 310 is rotated by a drive motor (not shown) as discussed above. The action of cam 310 imparts a

reciprocal motion to cam bearing surface 82 causing connecting rod 302 to move horizontally. This moves piston 300 in the direction of arrows 311. Movement to the left enlarges the effective volume of chamber 305 creating a relatively low pressure. This permits entry of sterile saline fluid from fluid entry port 312 (see also FIG. 1) through ball valve 306 under tension of spring 307.

Movement of piston 300 to the right decreases the effective volume of chamber 305 forcing sterile saline solution to exit via ball valve 309 under sufficient pressure to overcome the tension of spring 308. Note that ball valve 306 will be forced closed as piston 300 is moved to the right. The saline solution is expelled through high pressure tube 75.

Seals 301 and 303 and springs 307 and 308 are selected consistent with the fluid pressures to be developed. Bellows 304 provides an additional seal for the system. Cam 310 may be designed to provide a relatively smooth flow of sterile saline, or it may be implemented as a Geneva or similar cam to enhance the pulsatile delivery of the sterile saline to change the emulsification action at the distal tip of catheter 12.

Pressure plug 100 can be adjusted so that if the pressure reaches an upper limit, such as 30,000-40,000 psi, the pressure will be released and the safety monitor 96 will turn the motor off.

FIG. 2c is a schematic view of safety monitor 44. The emulsified thrombus is evacuated in line 314. If the entrance to the evacuation port becomes blocked, the pressure in line 314 will drop and cause membrane 322 to retract around line 314 which has an opening port 324 which has passage to the membrane. As the membrane retracts due to a blockage in the evacuation tube, the contacts 340 and 336 are opened and thereby trigger a relay 329 which will turn off the drive motor 328.

FIG. 2d is a cross-sectional view of an alternative source of pressurized fluid. This approach replaces the function of disposal piston pump 80. Using this technique, the high pressure tubing 118, plugs 53 and 48, tapered ring 119, and saline bag 95 are inserted into the conformal housing 46 and tightened down using threads 45. Chamber 43 is pressurized by supplying pressurized non-sterile water or other fluid through inlet 51 forcing sterile saline to exit from port 49 of tubing 118. A seal 81 is made between the bag 95 and the high pressure tubing 76 which delivers the high pressure saline. The high pressure tubing 118 is brazed into a tapered sealing ring 119. A seal is made between the bag 95 and the ring 119 and also between the bag 95 and end plug 48 by tightening down plug 53. The outer plastic tubing 76 is adhesively bonded to plug 53. Bottom plugs 61 and 69 are held in place by threads 63, 65, and 67 and sealed by seal 83 as plug 69 is tightened down.

Whenever employing this alternative embodiment, care must be exercised not to rupture sterile

saline bag 95 under the extreme pressures required by the present invention. High pressure fluid is supplied to tubing 85 from a positive displacement pump (not shown).

**FIG. 3** is a cross sectional view of manifold 20. Because this component is molded as two halves, which are solvent-bonded together, the view also happens to show one of the two halves. As explained above, catheter 12 is a two lumen catheter. In the preferred mode, each of the two lumens has two distinct functions. Therefore, manifold 20 serves to provide passage for a high pressure tubing and balloon inflation through one lumen and passage of a guide wire and evacuation through the other lumen.

The larger lumen of catheter 12 is lumen 110. It is used for passage of guide wire 18 (not shown in this view) and for evacuation of effluent and possible passage of an angioplasty dilatation catheter or angioscopic probe. Lumen 110 terminates inside the manifold 20 at the proximal end of the flexible tubular member and provides passage of a guide wire or other diagnostic or therapeutic device. Guide wire 18 is sealed by compressible circular seal 136 which is compressed by surface 140 as threaded knob 72 is tightened on threads 138. It is important to seal guide wire 18 in this way as guide wire 18 must be movable with respect to catheter 12 to properly manipulate distal tip 16 of catheter 12 into position.

Lumen 110 is also terminated at secondary branch 24. This is accomplished by removing a portion of the outer wall of lumen 110 at point 120. This provides fluid coupling between lumen 110 and lumen 134 of secondary branch 24.

The smaller lumen of catheter 12 is lumen 112. One of its functions is as a fluid passageway for the inflation of balloon 14. This function is accomplished by removing a portion of the outer wall of lumen 112 at point 114 to fluid couple lumen 112 to lumen 116 of secondary branch 26.

The remaining purpose of lumen 112 is to provide for passage of metallic tubing 118. Because of the extremely high pressures involved, the saline solution is conveyed in a metallic tubing 118, which is preferably stainless steel hypo tubing. To handle the pressures involved, the hypo tubing is run as a continuous length along catheter 12. The proximal end of metallic tubing 118 passes through the outer wall of lumen 112 and into secondary branch 25. A larger diameter hypo tube is brazed onto hypo tube 118 at point 123. This larger tubing is covered by protective plastic tubing 71. Manifold 20 is solvent-bonded together prior to assembly of the catheter, and points 124, 126, 128, 130 and 133 are used to introduce an adhesive which serves as a seal to separate each path and each lumen. Point 132 shows the bonding of the outer plastic tube which surrounds the high pressure supply tube to the manifold.

**FIG. 4** is a schematic view of manifold 20 wherein

all referenced elements are as previously described. This figure is purposely not drawn to scale to better illustrate the operation of manifold 20.

5 **FIG. 5a** is a close up view of balloon 14 and distal tip 16 of catheter 12. Attachment between catheter 12 and balloon 14 occurs at overlap points 144 and 146. These overlap points are sealingly attached with adhesive or heat sealing.

10 Catheter 12 is a dual lumen catheter extruded from rubber or a polymer as described above. Cap 150 is fixedly attached at the distal tip of catheter 12 as shown. Preferably cap 150 is made of a radiopaque metal such as platinum, tantalum or stainless steel to provide ease of location under fluoroscopy.

15 Extending beyond cap 150 is metallic tubing 118. This is necessary to permit the jet or jets which dispense the saline solution to be directed at cap 150 (i.e. the distal tip of lumen 110). Because metallic tubing 118 is so flexible, it must be backed by metal plate 156 to provide the necessary rigidity. Metallic tubing 118 is bent as explained below. To conform, metal plate 156 is angled to form rounded distal surface 160. This annular shaped tip would allow passage of a guide wire, angioscope, or angioplasty dilatation catheter.

20 **FIG. 5b** is a longitudinal sectioned view of the structure of **FIG. 5a**, wherein referenced elements are as previously described. Also shown in this view is balloon inflation port 148 which provides fluid communication between lumen 112 and balloon 14. Septum 142 separates lumen 110 from lumen 112. Lumen 112 is sealed distal to the balloon using an adhesive seal 113 attaching the high pressure tube 118 and filling lumen 112.

25 30 35 40 45 50 **FIG. 5c** is a view from the distal end of catheter system 10 wherein referenced elements are as described above. The central opening would allow passage of a guide wire, angioscope or angioplasty dilatation catheter.

Metallic tubing 118 is bent into a circular shape perpendicular to the axis of the catheter beginning at bend 152. Metal plate 156 bends at point 158 to provide rigidity at that point. Jet 164 is a small diameter orifice on the order of .0005 to .003 of an inch. It directs a stream of saline solution at cap 150 (i.e. mouth of lumen 110) at 5,000 to 30,000 psi. This pressure is sufficient to emulsify thrombus deposits located between jet 164 and cap 150. This stream of saline solution also creates a stagnation pressure about cap 150 sufficient to propel the emulsion into and through lumen 110 (see also **FIG. 1**). This stream of saline solution is of high velocity which creates a localized area of low pressure around the stream which attracts thrombus deposits for emulsification and removal.

55 **FIG. 6** is a cross-sectional view from the proximal end of catheter 12 to balloon 14, wherein referenced elements are as previously described. Metallic tubing

118 is shown within lumen 112. The cross-sectional area of lumen 112 which is in excess of that needed for metallic tubing 118 provides the fluid passageway for inflation of balloon 14. Lumen 162 of metallic tubing 118 has a diameter of about .003-.010 inch. It conveys saline solution at 1,000 to 30,000 psi through the main body of the catheter.

FIG. 7 is a cross-sectional view taken through balloon 14 and balloon inflation port 148. The remaining elements are as previously described.

FIG. 8 is a cross-sectional view taken distal to balloon 14. The distal end of the balloon inflation lumen is plugged with adhesive 113 to provide an enclosed space for balloon inflation.

FIG. 9 is a cross-sectional view taken just proximal of the saline solution jets. Shown in addition to jet 164 are jets 154a, 154b, 154c, and 154d, which are similar in size and range to jet 164. Jet 164 is directed generally back toward the evacuation channel to generate a stagnation pressure, create a localized area of low pressure to attract thrombus deposits, emulsify any thrombus which is brought into its path and keep the opening to the evacuation lumen clean and open.

Jets 154a, 154b, 154c, and 154d can number from zero to eight with a preferred number of three to six jets, although not limiting and are directed with some radial component toward the vessel wall as drawn and may also have some axial direction towards the evacuation opening. These jets remove thrombus which is attached to the vessel wall and establish a recirculation pattern which entrains thrombotic material and brings it into contact with jet 164 for further emulsification and removal.

FIG. 10 is a close up view of the distal end of an alternative embodiment of the present invention including balloon 204 which is located distal to the active components. Balloon 204, along with balloon 202, can be used to isolate a portion of the vessel during the procedure. Fluid recirculation between the balloons brings the thrombus into contact with the jet for emulsification and removal. In this embodiment, lumens 206 and 208 function as lumens 110 and 112, respectively. Cap 220 is similar to cap 150. A thermistor (not shown) can be used with either the preferred or alternative embodiment. The thermistor concept should only be added as a possibility which will help in monitoring the degree of occlusion and/or power delivery. Metal tube 212 has the same function as metal plate 156 in the preferred embodiment. Metallic tubing 210, bend 214 and jet 216 directly correspond to similar components in the preferred embodiment. An adhesive 221 and 223 is applied in the lumen of distal tubing 225 to provide an enclosed space and allow balloon 204 to be inflated through the distal balloon inflation port 219.

FIG.11 is a cross-sectional view of the alternative embodiment from proximal to balloon 202. In this

embodiment, a three lumen catheter is used. Lumen 206 is the largest lumen, which is used for passage of the guide wire and evacuation of the effluent. Annular space 222 is used for inflation of balloon 204 and for passage of metallic tubing 210. Lumen 226 provides for inflation of balloon 204. Annular space 224 could be used to permit an external device (not shown) to measure the pressure and/or temperature within the treatment area to determine when thrombus deposits are completely emulsified.

FIG. 12 is a cross-sectional view of the alternative embodiment as viewed through balloon 202. Shown is balloon inflation port 218.

FIG. 13 is a cross-sectional view of the alternative embodiment as viewed distal of balloon 202. Guide wire 228 is shown located within lumen 206.

FIG. 14 is a cross-sectional view of the alternative embodiment as viewed distal to cap 220.

FIG. 15 is a cross-sectional view of the alternative embodiment as viewed proximal to balloon 204. Shown is a jet 216 directed back towards the evacuation lumen and a plurality of jets numbered 217a, 217b, 217c and 217d, which are directed with some radial component toward the vessel wall. These outwardly directed jets may not be necessary since the distal balloon can be used to dislodge the thrombus off of the wall. Metal tubing 230 extends to the distal balloon for inflation.

FIG. 16a is a longitudinal sectioned view of safety monitor 44. It is placed over flexible membrane 330 of distal end 42 and flexible effluent tubing 54. Fluid communication is supplied by port 332.

FIG. 16b is a cross sectioned view of safety monitor 44. It functions much as a safety monitor with contacts 336 and 340 being closed whenever pressures are reduced due to blockage of the evacuation tube. Fluid communication to the membrane is supplied by port 332.

In another aspect the invention provides a thrombectomy device for removing thrombus from an occluded biological or synthetic vessel comprising:

- a tubular member (12) having passage means extended along the length thereof and an open inlet end (150) open to said passage means;
- means (76) having a passage (118) for carrying high pressure liquid extended through a second passage means (112) and a portion thereof located adjacent said tubular member, said portion having first orifice means (164) orientated to direct at least one first jet of liquid toward the open inlet end (150) of the tubular member; and,
- means connected to the means for carrying high pressure liquid for supplying high pressure fluid to said tube means whereby the first jet of liquid flows from the first orifice means to ablate thrombus in said vessel.

In another aspect the invention provides a thrombectomy device for removing thrombus from an

occluded biological or synthetic vessel comprising:

- a tubular member (12) having passage means (112) extended along the length thereof and an open inlet end (150) open to said passage means;
- means (76) having a passage (118) for carrying high pressure liquid extended through said passage means (112) and a portion thereof located forwardly of said tubular member, said portion having orifice means (164) orientated to direct at least one jet of liquid toward the open inlet end (150) of the tubular member and means connected to the means for carrying high pressure liquid for supplying high pressure fluid to said tube means whereby the jet(s) of liquid flows from the orifice means to attract and ablate thrombus in said vessel for removal through said passage means; and
- controlled metering means connected to the tubular member to control the flow of liquid and ablated thrombus in said passage means at a rate of flow generally the same as the rate of flow of liquid from the orifice means.

In a further aspect the invention provides a method of treating a vessel and removing a thrombus deposit comprising:

- advancing a catheter to the site of said thrombus deposit;
- supplying high pressure fluid through said catheter while containing and localizing said thrombus deposit;
- attracting and emulsifying said thrombus deposit; and,
- evacuating said emulsified thrombus deposit under positive pressure.

Said method optionally includes inflating said catheter to dilate an occlusion of said vessel.

Preferred forms of the invention have one or more of the following features:

- (a) nose means (156, 160) mounted on the tubular member for holding said end of the tube means (76), especially where the nose means includes an annular tip at the forward end thereof surrounding the terminal portion of the end of the tube means.
- (b) the end of the tube means (76) has a generally arcuate portion and said at least one orifice (164) is located in said arcuate portion. The arcuate portion can, for example, have a C-shape extended transversely relative to the longitudinal axis of the tubular member.
- (c) nose means (156, 160) mounted on the tubular member for holding the end of the tube means, said nose means having an annular tip surrounding the generally arcuate portion of the end of the tube means (76).
- (d) the means (80) for supplying high pressure fluid to said tube means (76) operates to supply

fluid at a pressure of at least 1000 psi to said tube means.

(e) the balloon is a formed balloon which can dilate the vessel during or following the removal of the thrombus.

(f) balloon means mounted on the tubular member adjacent the open outlet end thereof generally to center the portion of the means for carrying high pressure liquid within the vessel, and means to inflate the balloon means. The balloon can, for example, include a generally transverse forward end wall and a cylindrical side wall joined to the end wall.

(g) the tubular member has first passage means open to the interior of said balloon means, said first passage carrying fluid to inflate the balloon means.

## 20 Claims

1. A thrombectomy catheter characterised in that it comprises:
  - a passage (112) for the supply of a liquid under pressure to the site of the thrombus;
  - means (164) to direct said liquid so as to dislodge the thrombus;
  - a passage (110) to convey from said vessel thrombus effluent containing thrombus thus dislodged; and
  - a regulator (60) to match the flow of the effluent and the flow of said liquid supply.
2. A catheter according to Claim 1, which includes one or more balloons (14) which can be expanded temporarily to obstruct said vessel and thereby confine the thrombus prior to removal of the thrombus from said vessel.
3. A catheter according to Claim 2, which includes a fluid supply means (32, 34) to supply a fluid to expand the balloon in said vessel.
4. A thrombectomy catheter comprising
  - means for localizing a thrombus deposit;
  - means coupled to said localizing means for attracting and emulsifying said thrombus deposit; and
  - means coupled to said emulsifying means for evacuating said emulsified thrombus deposit under positive pressure.
5. A thrombectomy device for removing thrombus from an occluded or obstructed biological or synthetic vessel characterised in that it comprises:
  - a flexible tubular member (12) having a first passage (112) and a second passage (110)

extended along the length thereof, said first passage (112) having a first end and a second end, said second passage having an open inlet end (150) and an outlet end (120);

b. tube means (76) having a passage for high pressure liquid extended through said first passage (112) and second end thereof, said tube means (76) having an end located forwardly of the open inlet and of the second passage (110) said end of the tube means having a first orifice (164) orientated to direct a first jet of liquid toward the open inlet end (150) of the second passage;

c. means (80) connected to the tube means (76) for supplying high pressure fluid to said tube means whereby the first jet of liquid flow from said first orifice (164) to attract and ablate thrombus in the vessel;

d. controlled metering means (60,62,64,66) connected to the tubular member (12) to control the flow of liquid and ablated thrombus from said second passage (110) at a rate of flow generally the same as the rate of flow of the jet of said liquid;

e. balloon means (14) mounted on said tubular member (12) adapted to be expanded into engagement with the biological or synthetic vessel to help contain and localize the thrombotic material in a region near the second end of the tubular member; and,

f. means (32,34) connected to the tubular member (12) for supplying fluid under pressure to the first end of the first passage (112) whereby said fluid flows through said opening (148) and expands the balloon means.

6. A device according to any of Claims 1 to 5 which includes at least one orifice (154) oriented to direct at least one further jet of said liquid with some radial directional compency relative to the longitudinal axis of the second passage (110) whereby said further jet helps dislodge thrombus from the vessel wall and set up a recirculation pattern which entrains the thrombus and brings it into proximity of the first jet (164) for further emulsification and removal.

7. A device according to Claim 5 or 6, wherein said tube means (76) comprises a metal tube (118) extended through said first passage (112) of said tubular member (12).

8. A device according to Claim 6 or 7, wherein the means (80) for supplying high pressure fluid to said tube means (76) includes a housing having a chamber, a flexible bag containing a liquid located in said chamber, means connecting the bag to said tube means (76) to allow liquid to flow from the bag into the tube means, and means to supply fluid under pressure into said chamber to compress said bag and fluid therein, whereby fluid under high pressure flows through said tube means and is discharged through said first (164) and second (154) orifices into said vessel to attract and ablate thrombus therein.

9. A device according to any of Claims 5 to 8, wherein the controlled metering means (60, 62, 64, 66) comprises a positive displacement pump and control means for regulating the operation of the pump to limit the rate of flow of liquid out of the second passage (110) to about the rate of flow of liquid out of the orifices (164, 154).

10. A device according to Claim 9, wherein the pump is a roller pump having a tube connected to the tubular member, motor means for operating the pump, and said control means being operable to control the operation of the motor means thereby to control the operation of the pump.

11. A device according to Claim 5, wherein the high pressure fluid is supplied by a disposable positive displacement pump (80).

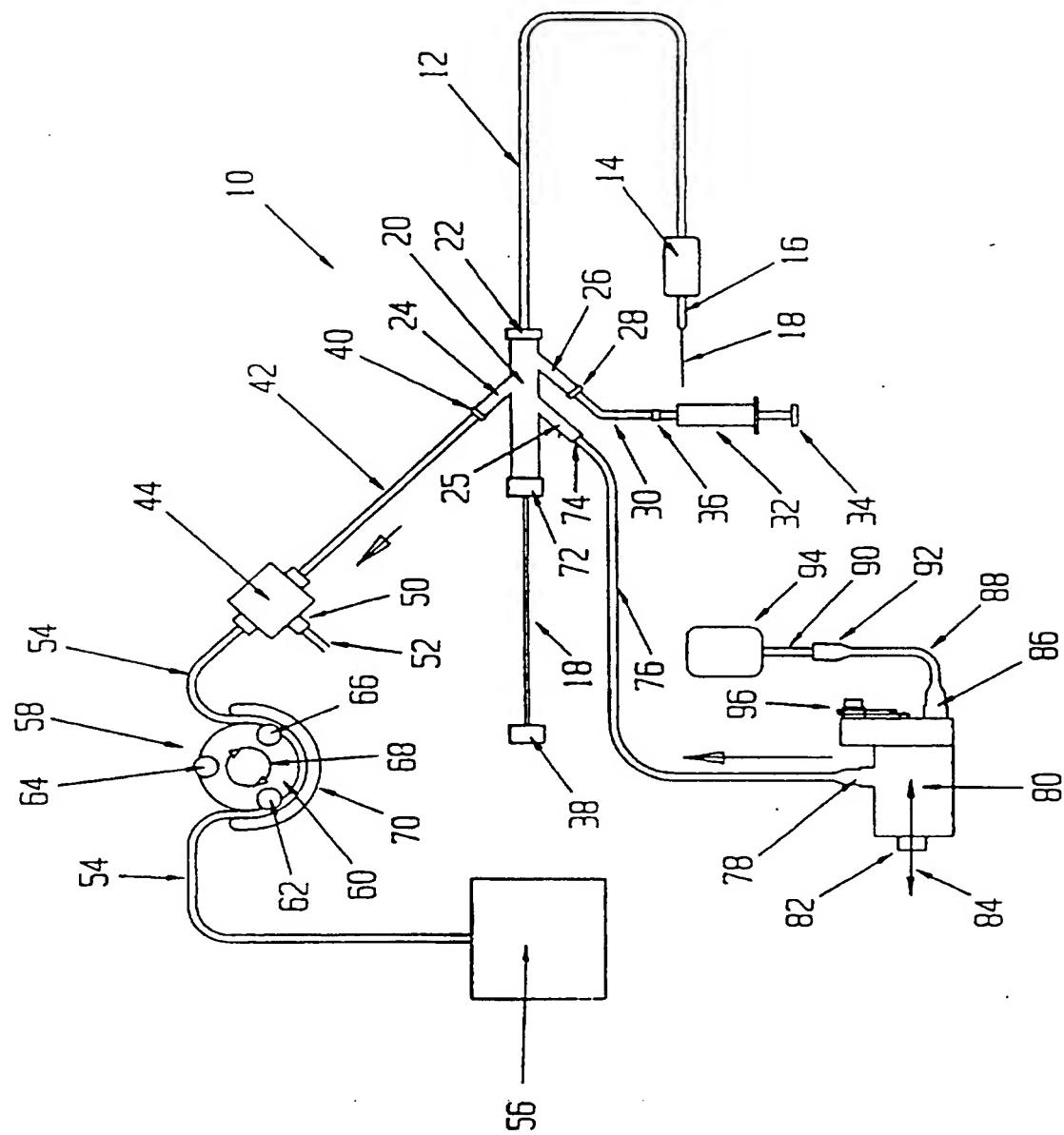


FIG. 1

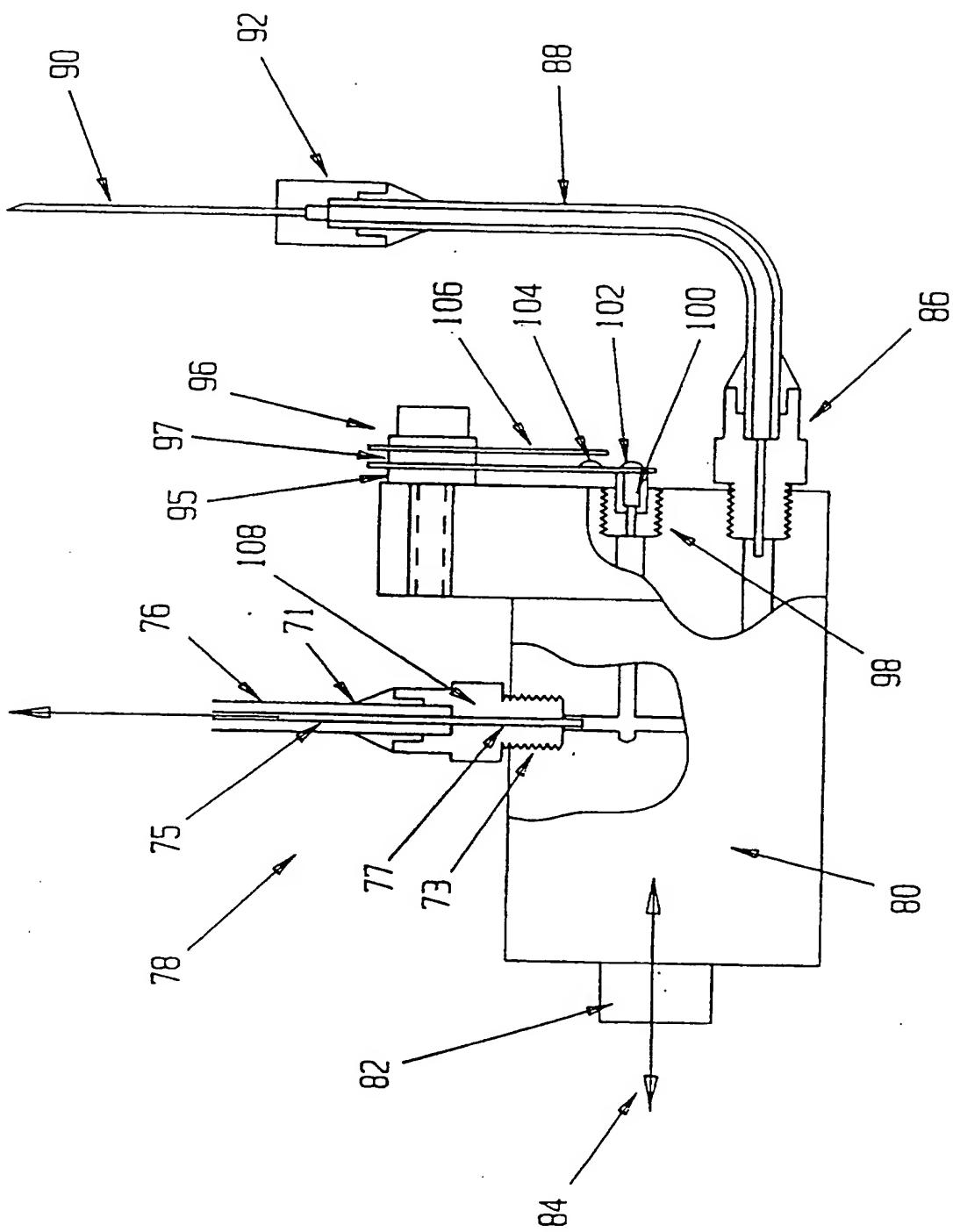


FIG. 2a

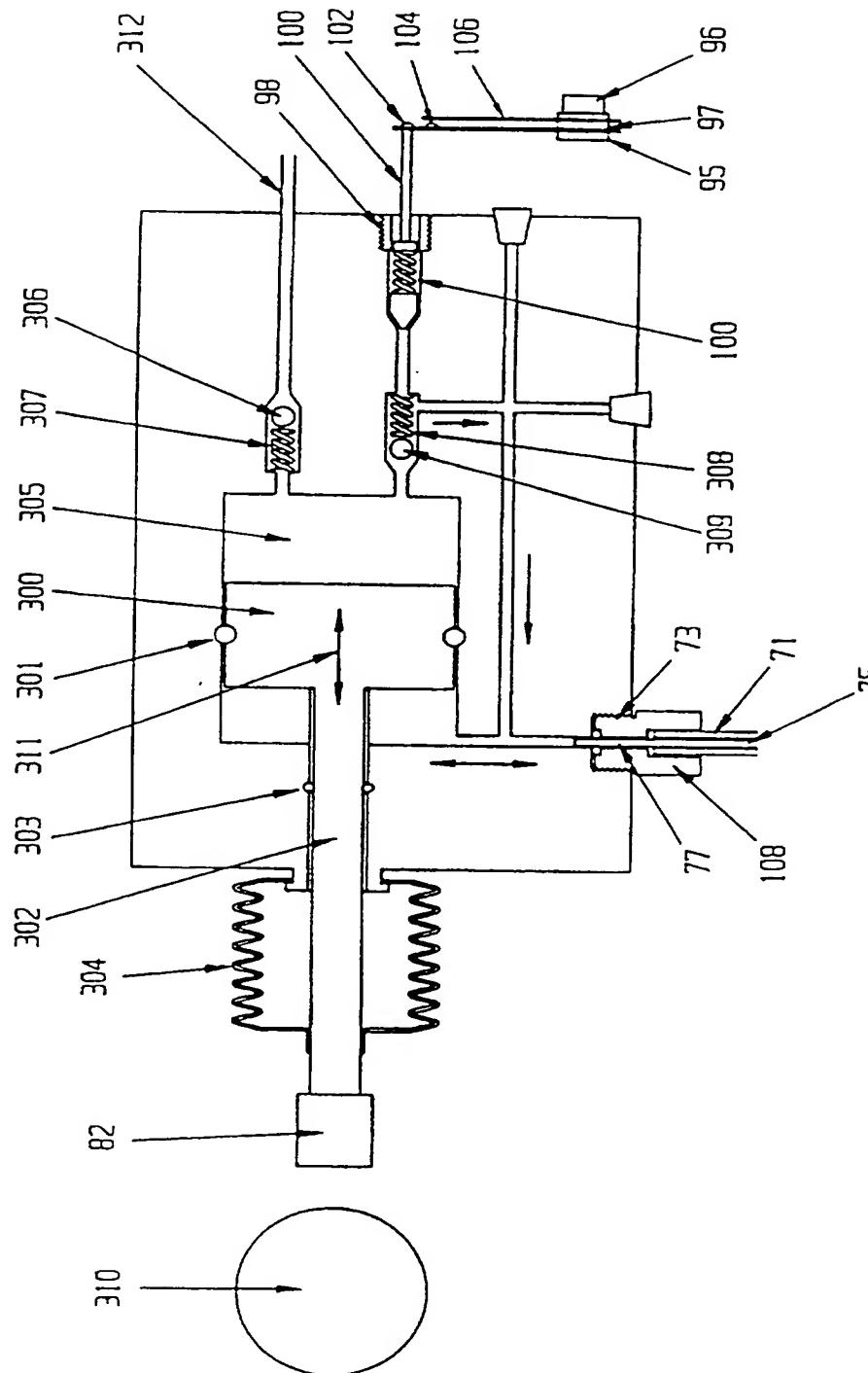


FIG. 2b

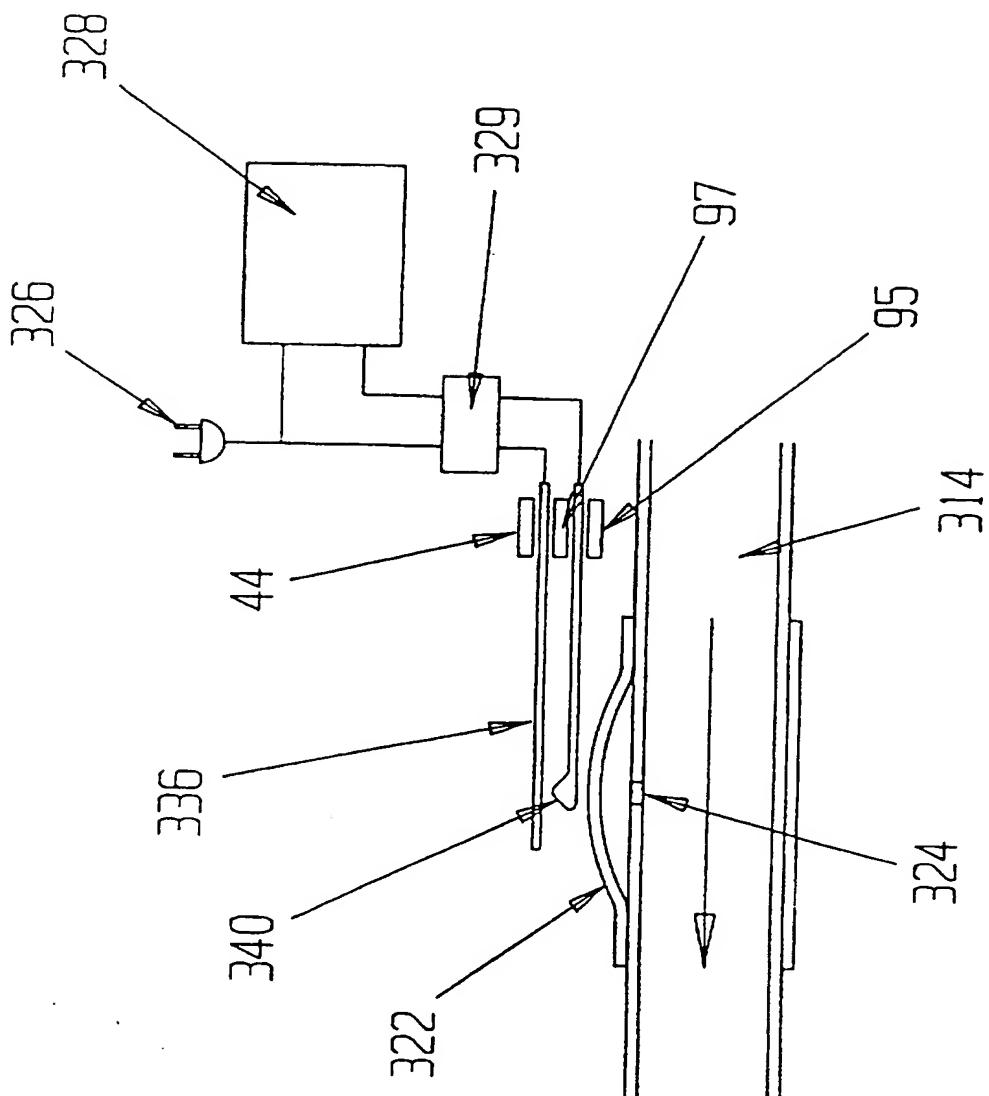


FIG. 2C

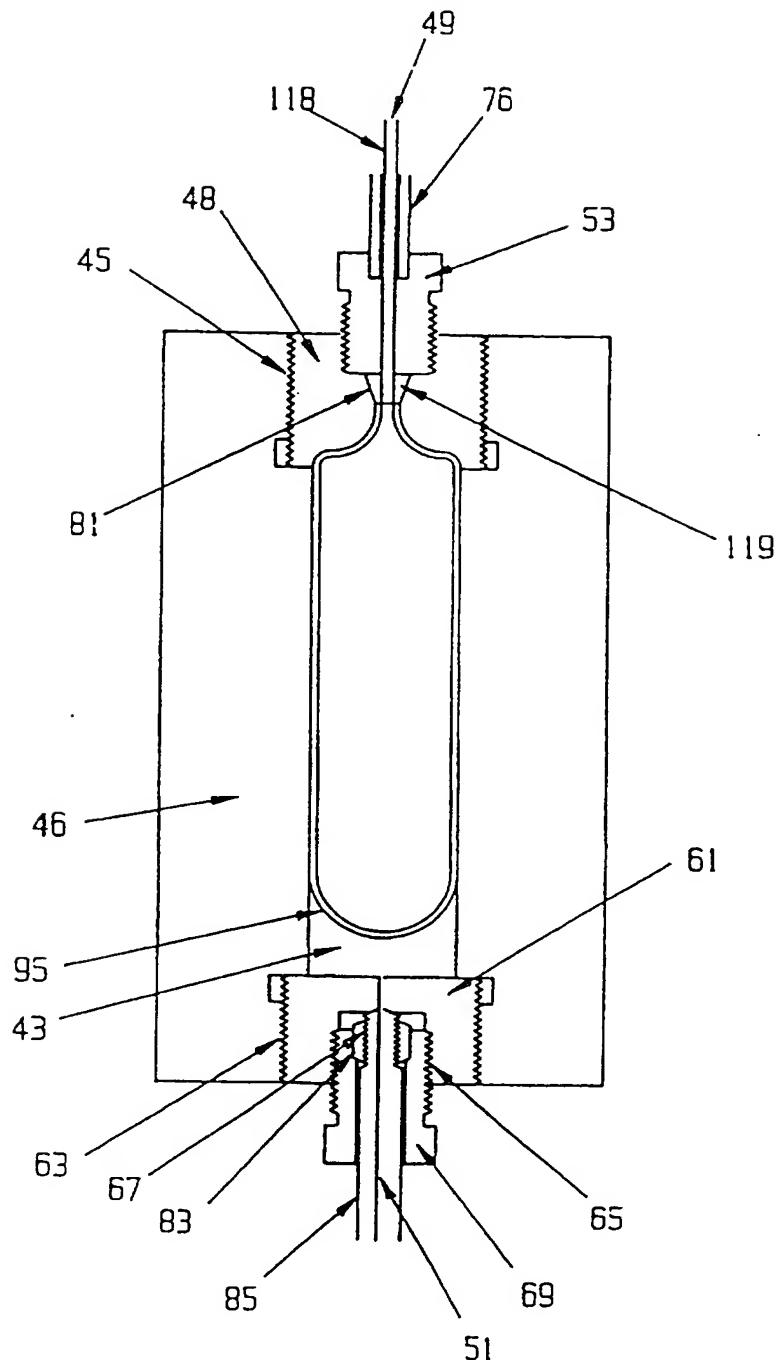


FIG. 2d

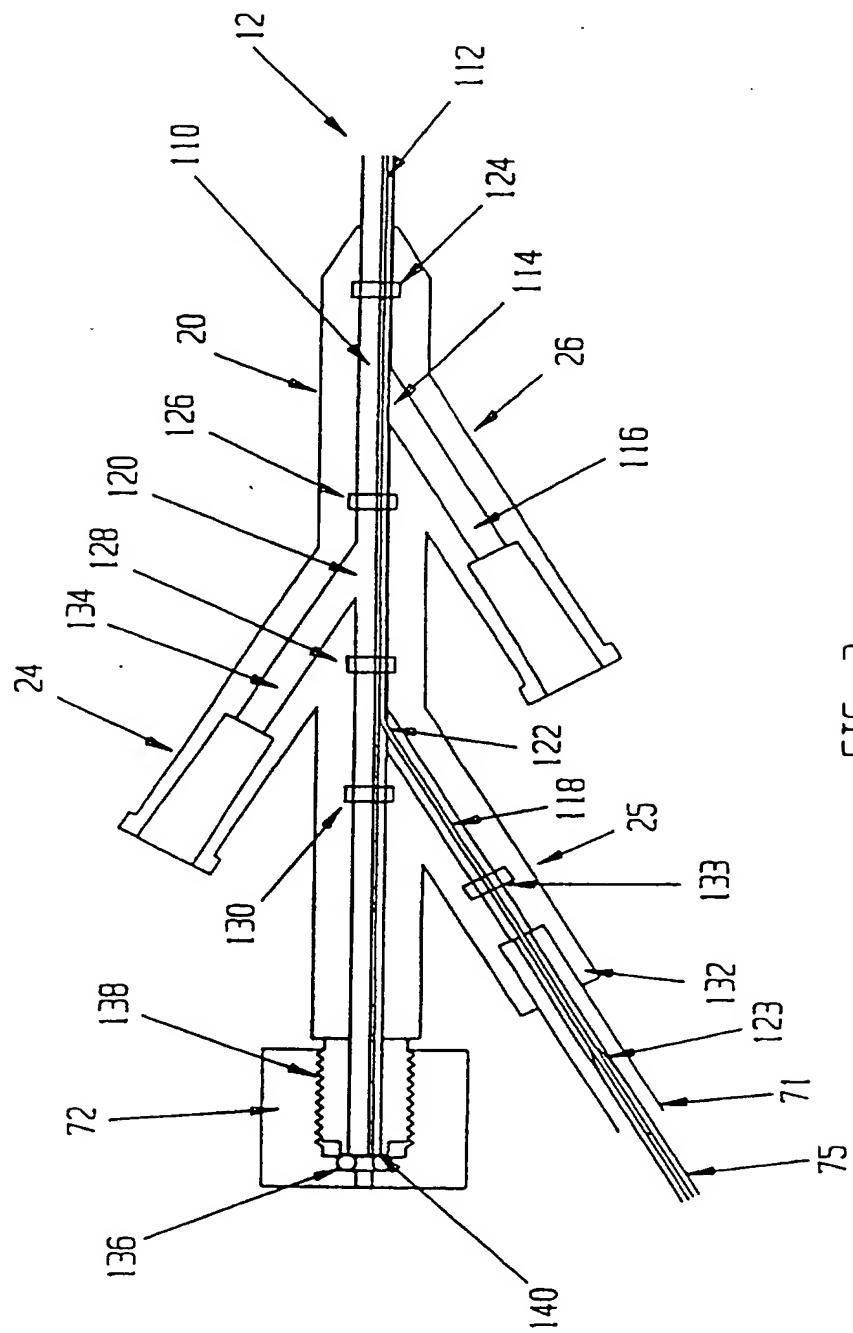


FIG. 3

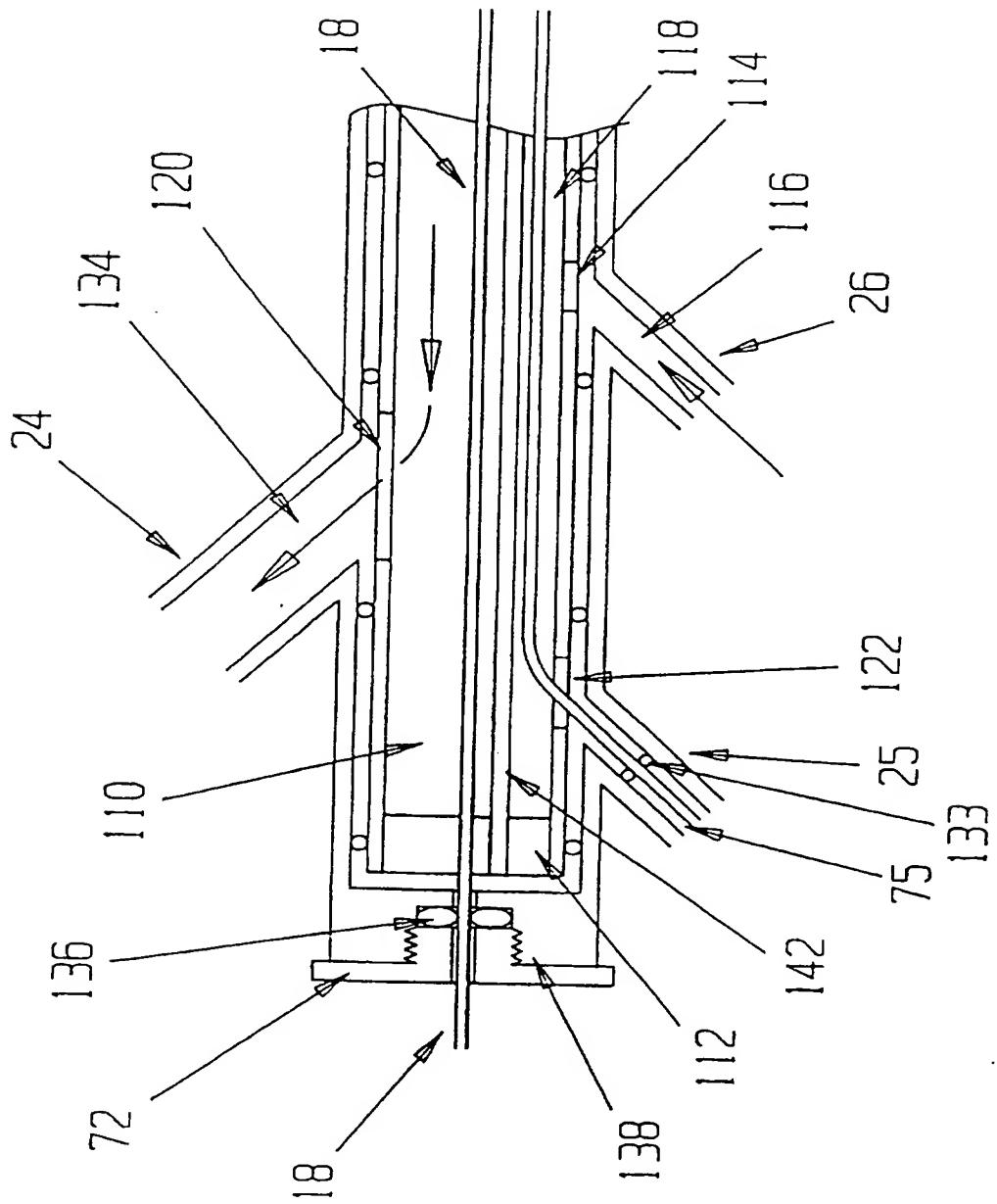


FIG. 4

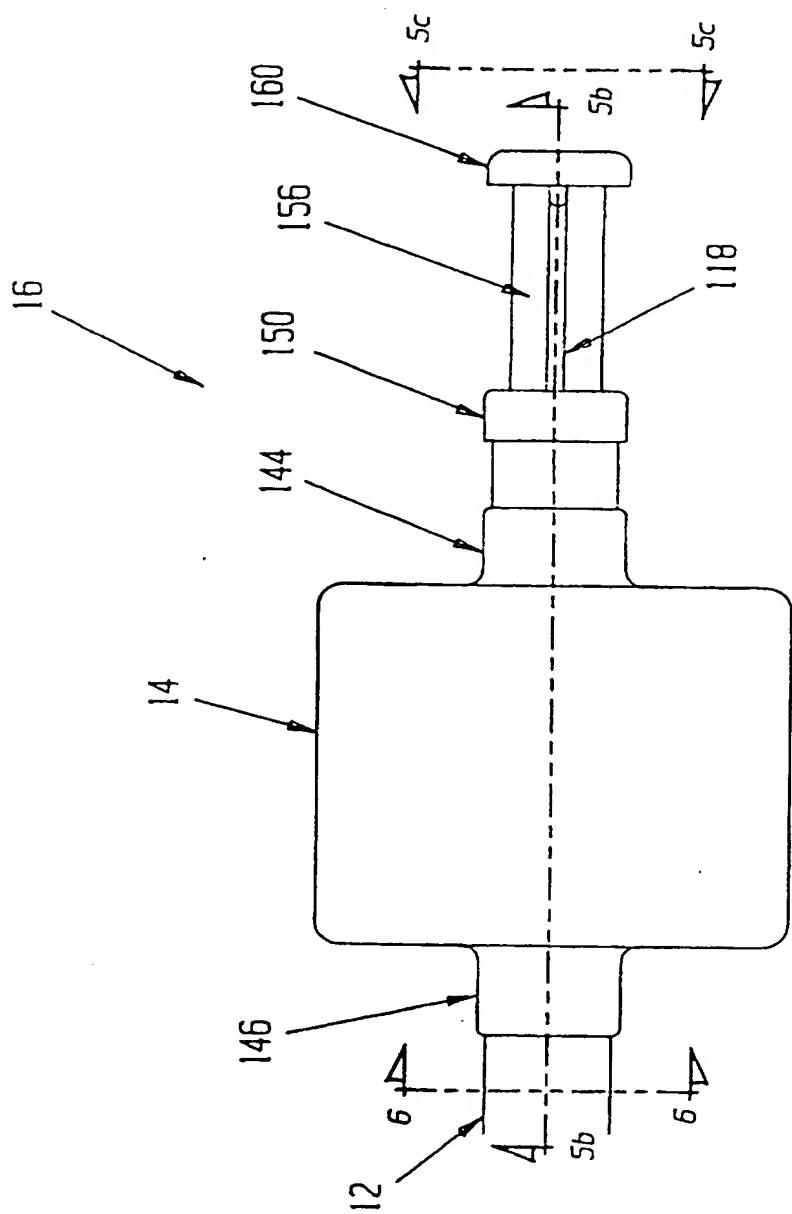


FIG. 5a

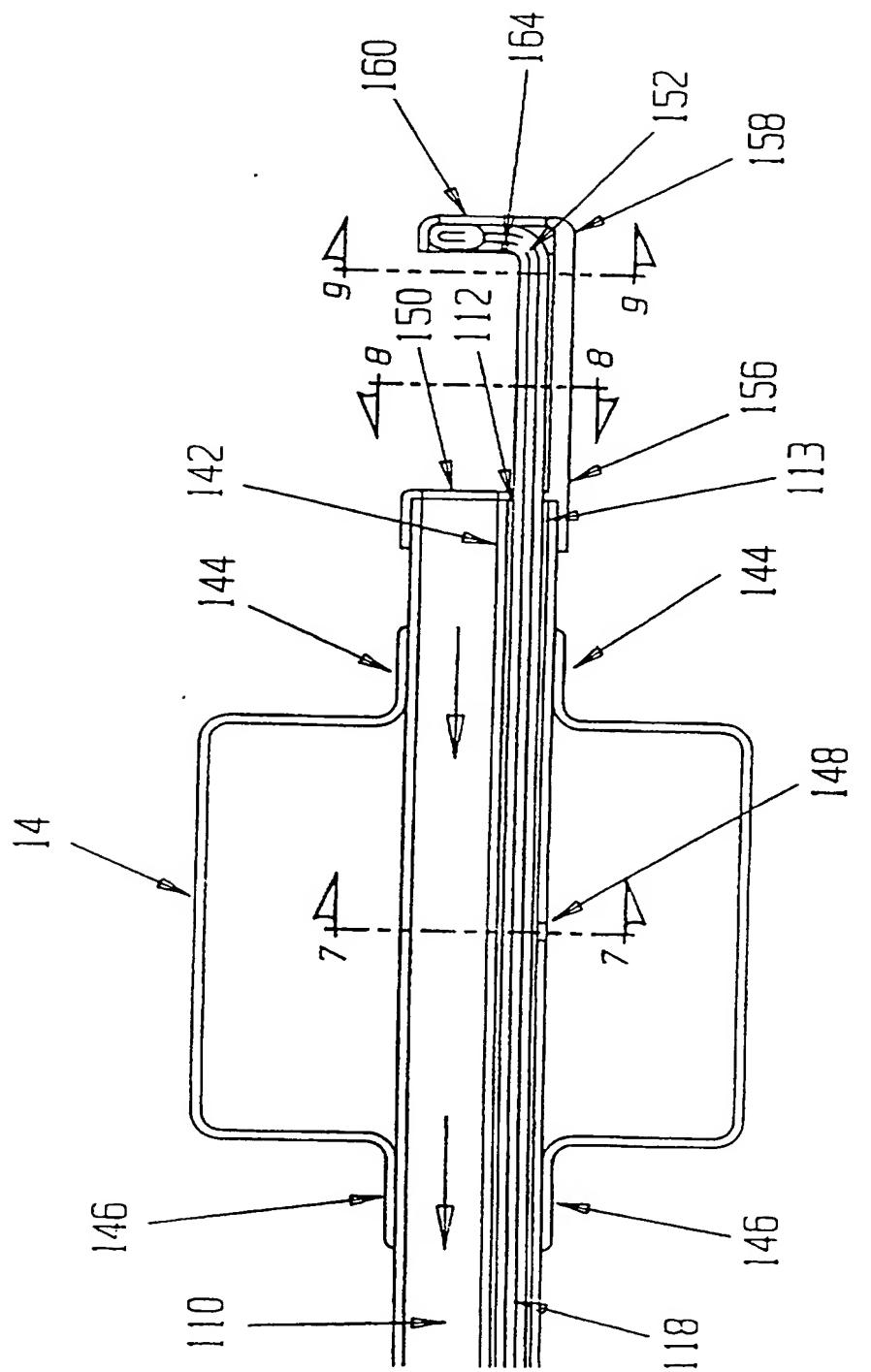


FIG. 5b

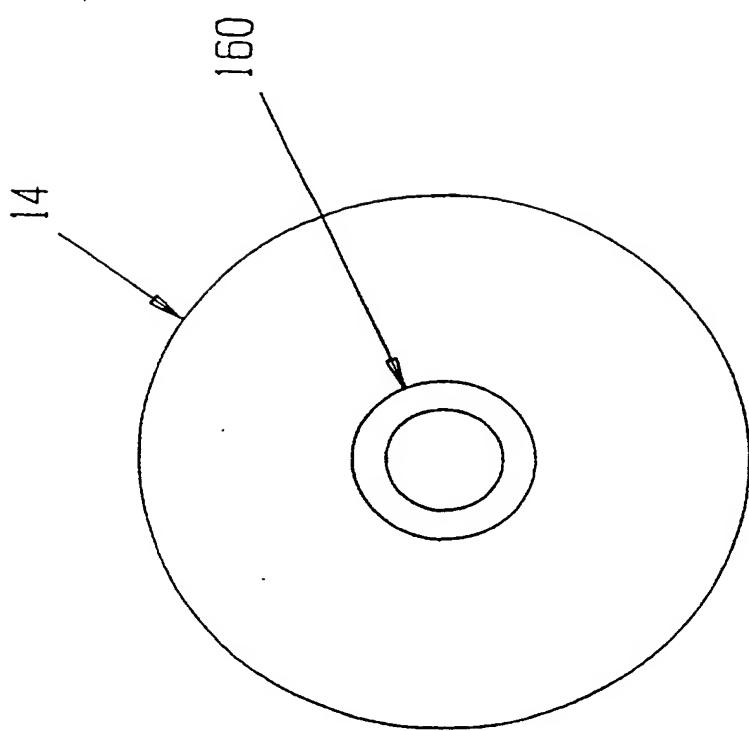


FIG. 5c

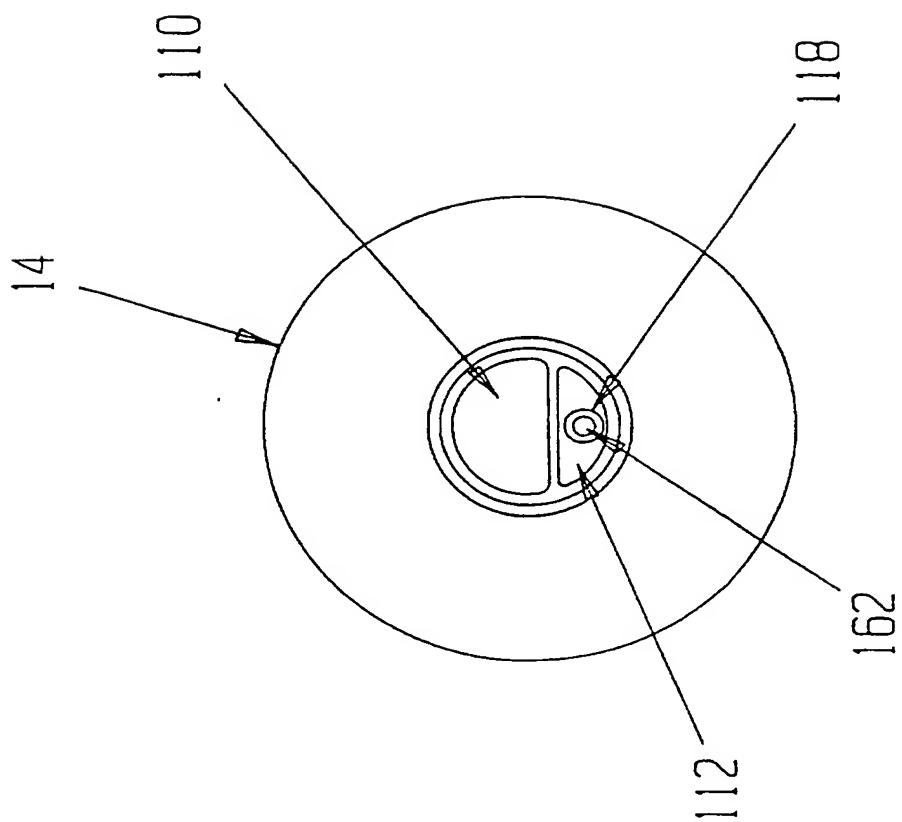


FIG. 6

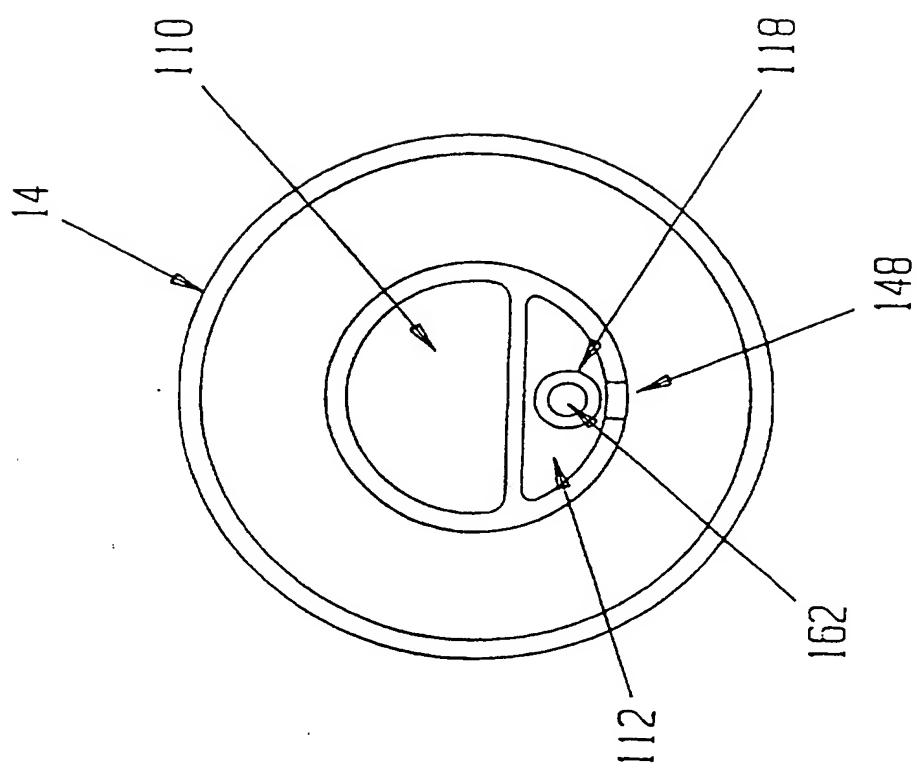


FIG. 7

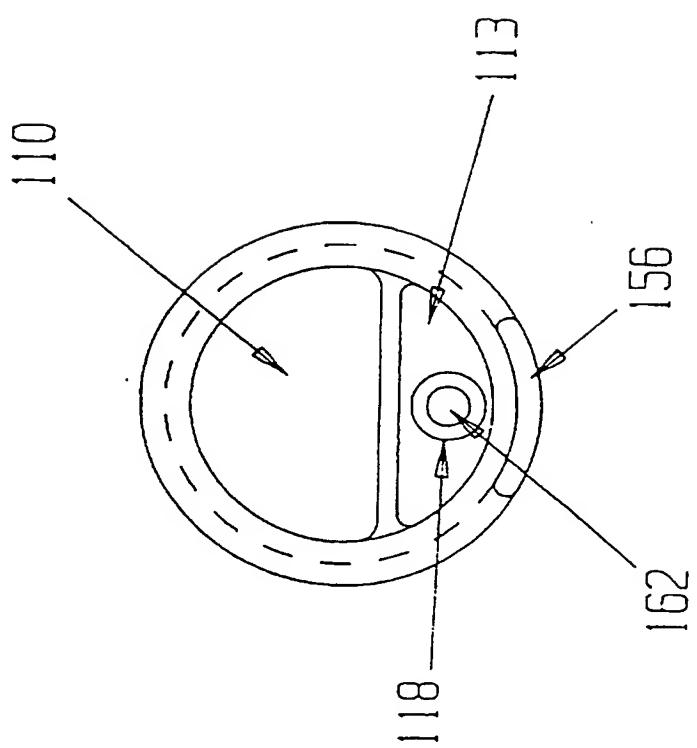


FIG. 8

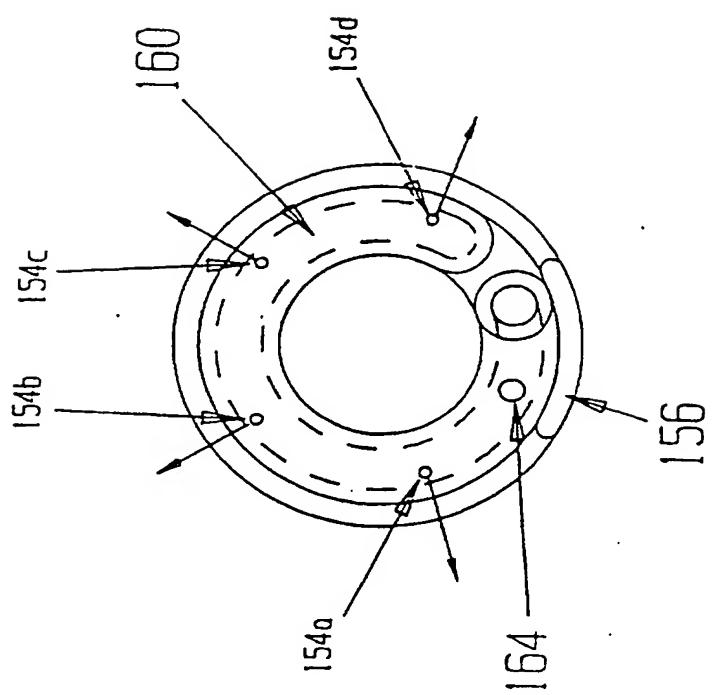


FIG. 9

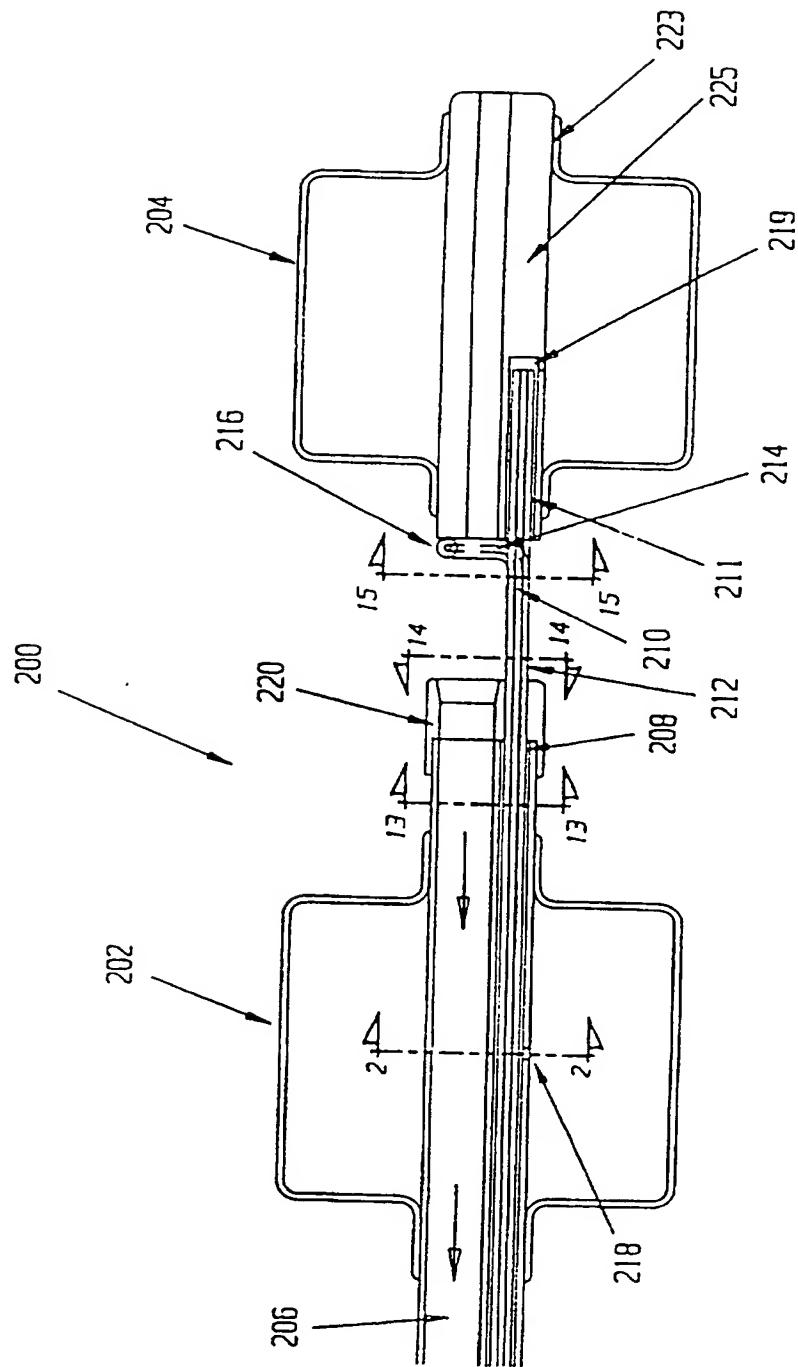


FIG. 10

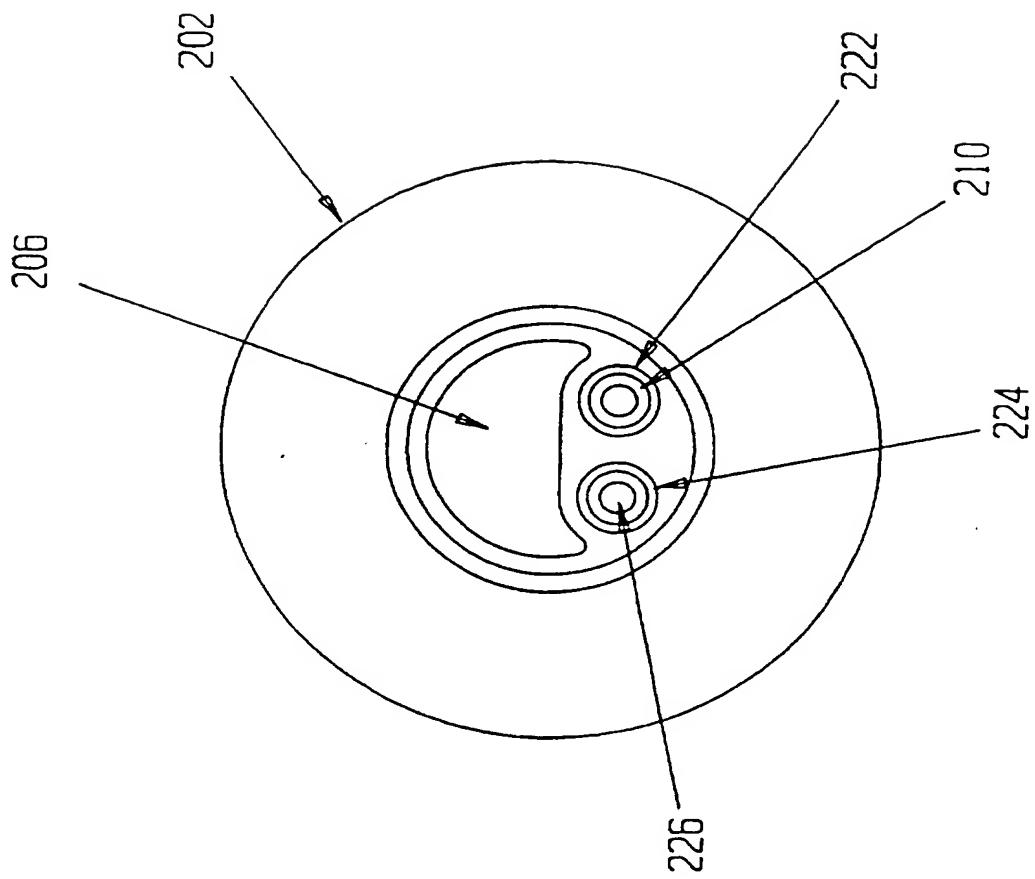


FIG. 11

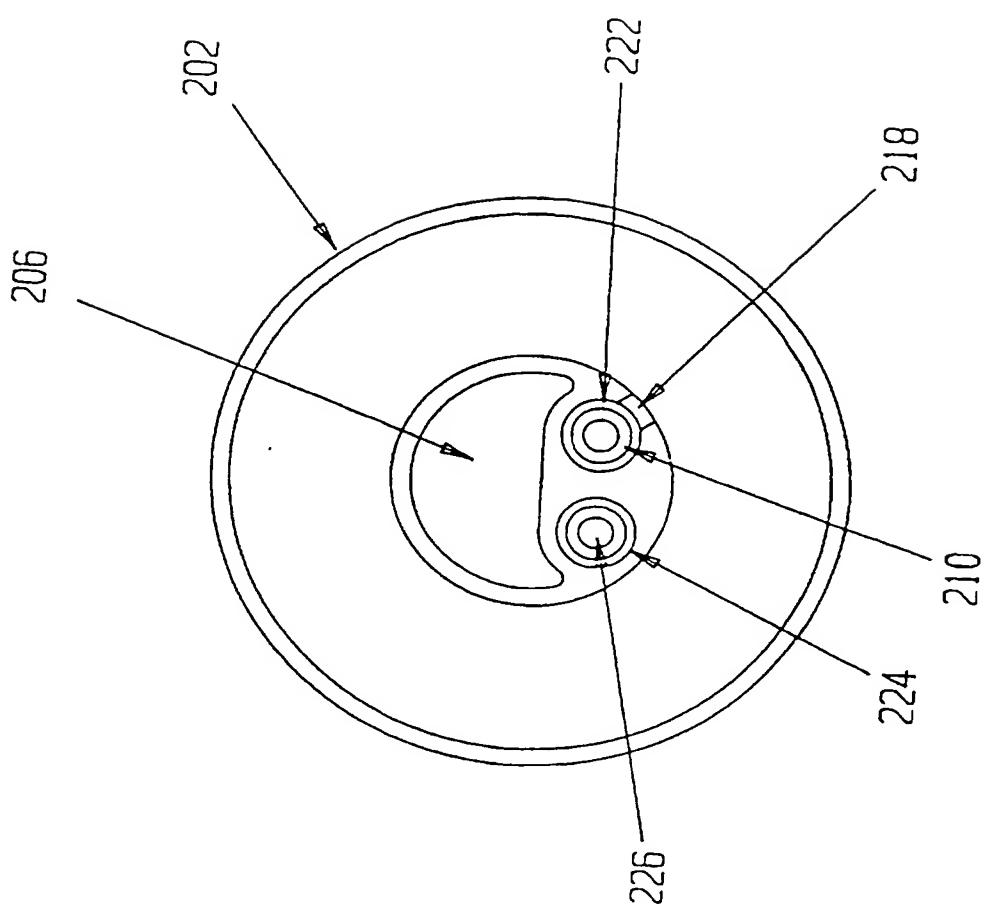


FIG. 12

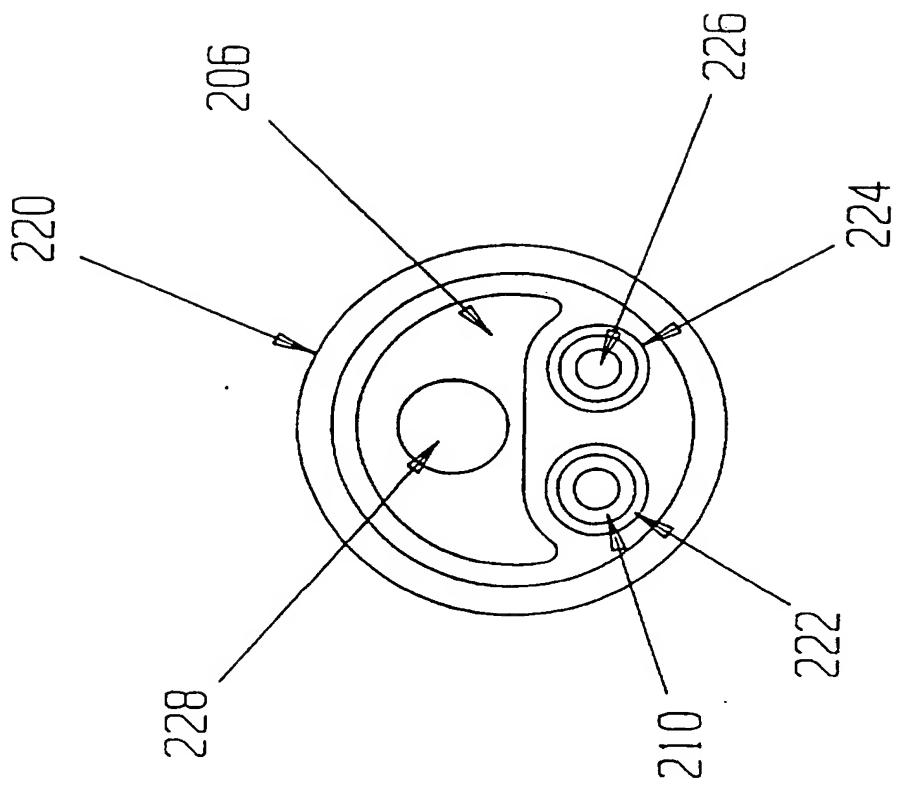


FIG. 13

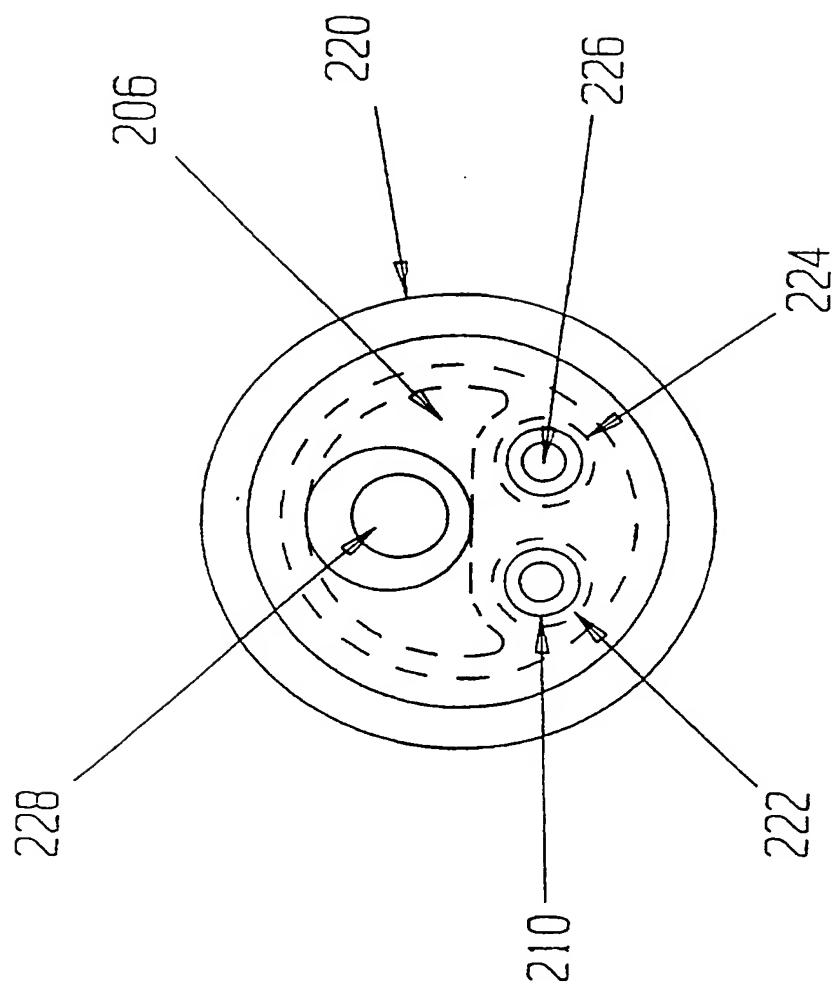


FIG. 14

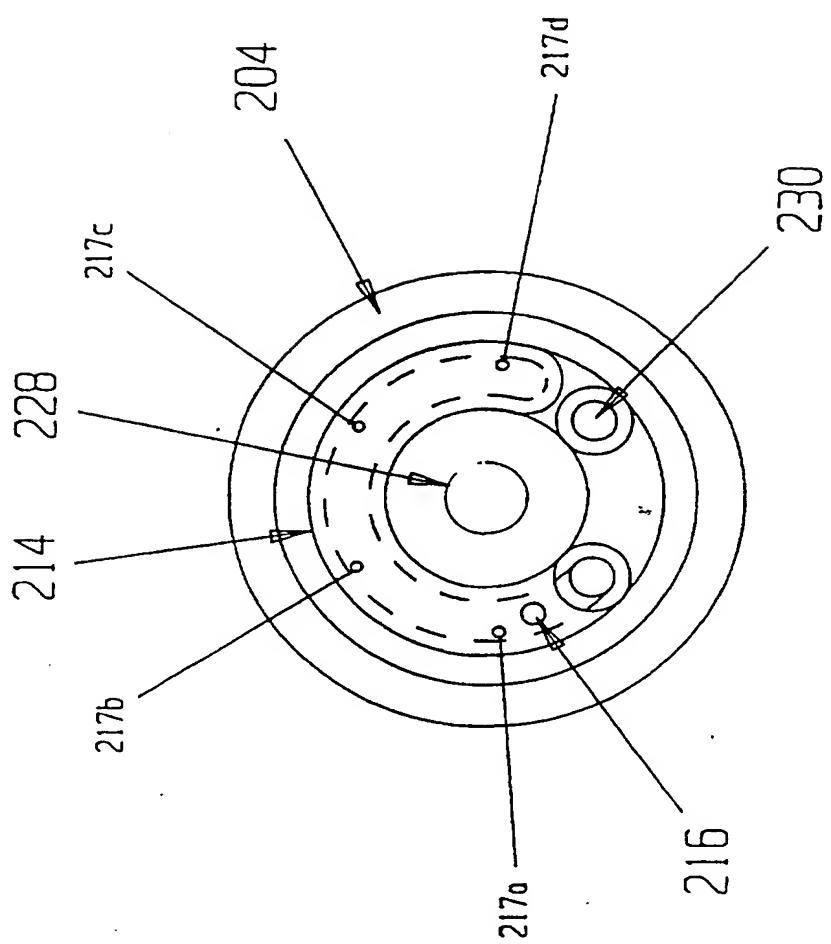
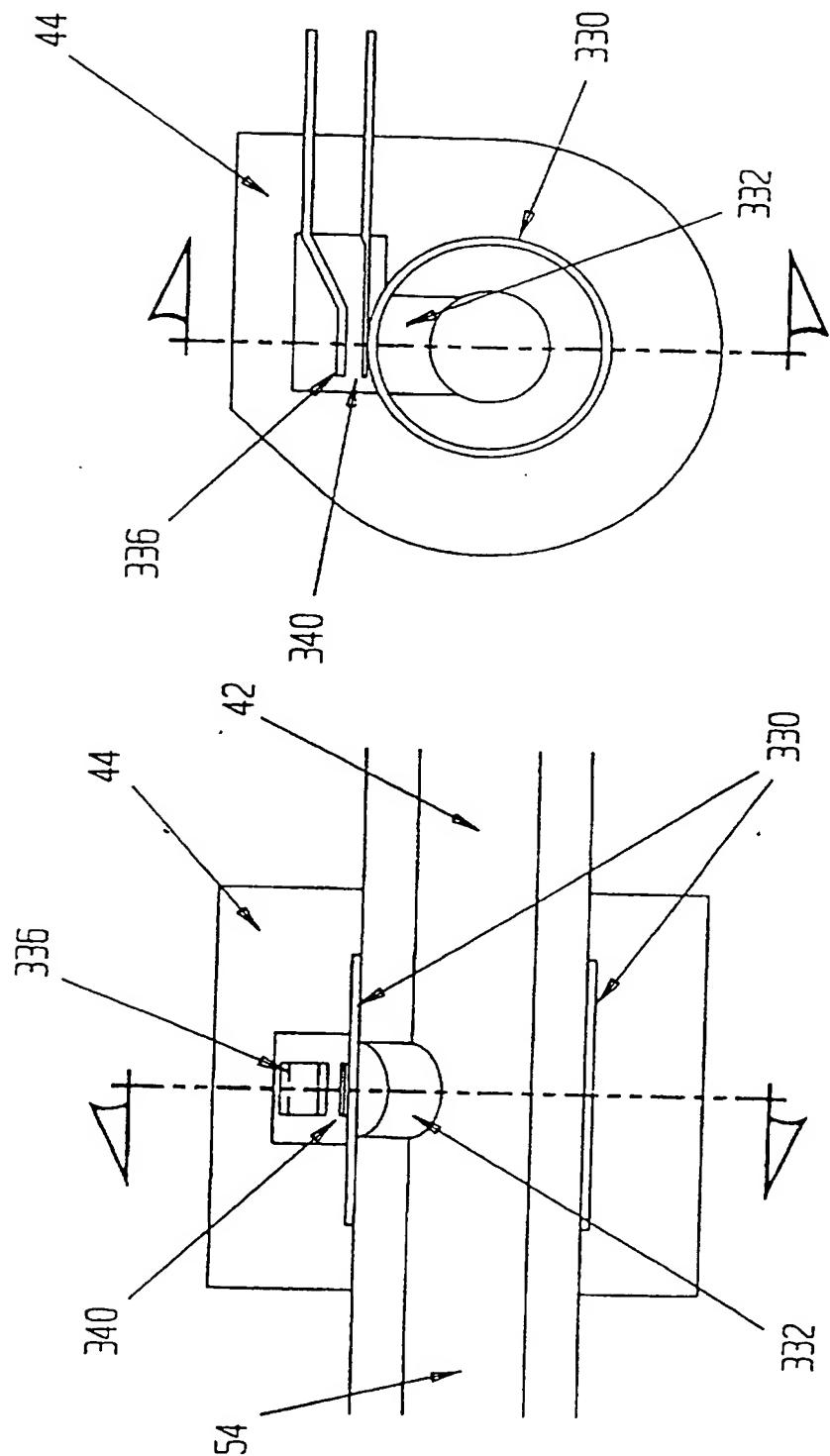


FIG. 15





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## EUROPEAN SEARCH REPORT

Application Number

EP 91 30 7140

#### **DOCUMENTS CONSIDERED TO BE RELEVANT**

DOCUMENTS CONSIDERED TO BE RELEVANT					
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. CL.5)		
Y	WO-A-9 005 493 (SVEOMAN) * page 2, line 15 - page 3, line 14 * * page 4, line 28 - page 5, line 10; claim 15; figures 1,2 * ---	1-11	A61B17/22		
Y	EP-A-0 251 512 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) * column 5, line 7 - line 26; figure 1 * ---	1-11			
A	DE-A-3 705 339 (SIEMENS) * column 4, line 31 - column 5, line 15; figure 2 * ---	1,4,5			
A	DE-A-3 421 390 (SCHUBERT) * page 34, line 21 - page 35, line 4; figure 16 * ---	6			
A	EP-A-0 232 678 (NERACHER) * column 2, line 28 - line 41; figure 2 * ---	7			
A	US-A-4 913 698 (ITO ET AL.) * column 2, line 67 - column 3, line 8; figures 1,3 * ---	8	TECHNICAL FIELDS SEARCHED (Int. CL.5)		
A	GB-A-1 571 459 (INSTAVAC) * claim 1; figure 1 * -----	11	A61B A61M		
The present search report has been drawn up for all claims					
Place of search	Date of completion of the search	Examiner			
THE HAGUE	15 NOVEMBER 1991	MOERS R.			
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